UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JONNIE HOMYK, et al.,

Plaintiffs,

v.

CHEMOCENTRYX, INC., et al.,

Defendants.

Case No. 21-cv-03343-JST (LJC)

ORDER DENYING RELIEF SOUGHT BY LEAD PLAINTIFF IN JOINT DISCOVERY LETTER BRIEF

Re: ECF No. 99

Before the Court is the parties' Joint Discovery Letter Brief. ECF No. 99. Lead Plaintiff Indiana Public Retirement System seeks an order authorizing it to provide the U.S. Food and Drug Administration (FDA) with deposition exhibits and testimony marked as confidential pursuant to the Protective Order governing this case (ECF No. 69) by Defendants ChemoCentryx, Inc. (ChemoCentryx), and Thomas J. Schall, President and CEO of ChemoCentryx. *Id.* at 1.[1] Lead Plaintiff contends that this disclosure and use of the material is necessary to allow the FDA to provide testimony by affidavit or sworn declaration. *Id.* The Court held a hearing on the matter on March 5, 2024. ECF No. 127. After the hearing, per the Court's order, Lead Plaintiff filed a copy of its subpoena to the FDA and its original request for deposition testimony under 21 C.F.R. § 20.1. ECF Nos. 128, 129. On March 11, 2024, Lead Plaintiff also filed a copy of a "revised" request, dated six days after the original request, which purportedly reflect meet-and-confer discussions between counsel for Lead Plaintiff and the FDA.[2] ECF No. 135.

[1] Unless specified otherwise, the Court refers to the PDF page number generated by the Court's e-filing system.

[2] The Court's deadline for Lead Plaintiff to file the 21 C.F.R. § 20.1 request materials was March 7, 2024. ECF No. 128. Lead Plaintiff filed the subpoena and its original request to the FDA for deposition testimony one day before the deadline, on March 6, 2024. ECF No. 129. Its filing of the "revised" request, however, was done four days after the deadline without leave of court and

Having read the Joint Discovery Letter Brief submitted by the parties and carefully considered their arguments and relevant authority, the Court hereby **DENIES** Lead Plaintiff's request for a court order allowing it to disclose ChemoCentryx's confidential documents for the reasons discussed herein.

I. BACKGROUND

The factual background of this case is thoroughly detailed in the "Background" section of Judge Tigar's Order Granting in Part and Denying in Part Defendants' Motion to Dismiss. ECF No. 50 at 1–5. The undersigned fully incorporates by reference that factual background into this Order.

In the Joint Discovery Letter Brief, filed on January 16, 2024, Lead Plaintiff asserts that it wants to provide the FDA with certain deposition exhibits and testimony, which were all designated as confidential by ChemoCentryx pursuant to the Protective Order. *See* ECF No. 69. The material at issue consists of the first 49 exhibits marked at deposition to date, as well as deposition testimony of: (1) Dr. Richard Glassock, who served as a member of the Data Monitoring Committee (DMC), a committee empaneled in connection with the FDA's evaluation of ChemoCentryx's New Drug Application (NDA) for avacopan; and (2) Dr. Willis Maddrey, a liver expert retained by ChemoCentryx, who analyzed data from the Phase III clinical trial set up to evaluate avacopan in connection with the NDA (the Advocate Trial).[3] ECF No. 99 at 1. The deposition exhibits generally contain internal ChemoCentryx communications, as well as communications between ChemoCentryx and the DMC, regarding results from the Advocate Trial as well as avacopan's safety and efficacy.[4] ECF No. 99 at 2.

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with no explanation as to the reason for the late filing. Nor was Lead Plaintiff's filing permitted by the undersigned's Standing Order, Section (F), governing discovery disputes, or otherwise permitted by the Court's Civil Local Rules. Nor did Lead Plaintiff file a motion seeking leave of the Court to submit its supplemental filing. The filing was clearly improper. Nevertheless, the Court will not strike it from the record, and will consider the revised request for purposes of ruling on the Joint Discovery Letter Brief.

[3] As of the filing of the Joint Discovery Letter Brief, the depositions of Dr. Glassock and Dr. Maddrey were not yet complete, as Defendants still needed to complete their cross-examination of the two witnesses. ECF No. 99 at 6, n.1.

[4] Concurrently with the filing of the Joint Discovery Letter Brief, Lead Plaintiff filed an Administrative Motion to Consider Whether Another Party's Materials Should Be Sealed, filing under seal portions of the Joint Discovery Letter Brief as well as Exhibits E–I thereto. ECF No.

On October 11, 2023, Lead Plaintiff sent a letter to Defendants asserting its position that the Protective Order allows it to share these documents with the FDA for the purpose of obtaining the agency's testimony. ECF No. 99-2 ¶ 2. Defendants responded on October 26, 2023, stating that they did not consent to the disclosure of confidential documents produced by ChemoCentryx for that purpose, which they argued was prohibited by the Protective Order. ECF No. 99-4 at 2.

On November 14, 2023, Lead Plaintiff served a subpoena on the FDA for deposition testimony regarding avacopan, the NDA, and the Advocate Trial.[5] ECF No. 129-1. The subpoena is subject to the FDA's *Touhy* regulations, which prohibit FDA employees from providing testimony before any tribunal pertaining to information acquired in the discharge of their official duties except when the Commissioner (or an employee designated to act on their behalf) determines that "such testimony will be in the public interest and will promote the objectives" of the Federal Food, Drug, and Cosmetic Act, as well as the mission of the FDA. 21 C.F.R. § 20.1(c); *see also U.S. ex rel. Touhy v. Ragen*, 340 U.S. 462, 468 (1951) (holding that a government agency can validly issue regulations restricting the availability of its personnel to be subpoenaed in private litigation in part because of "the variety of information contained in the files of any government department and the possibilities of harm from unrestricted disclosure in court.") Lead Plaintiff included a cover letter with its subpoena explaining why it believed that the FDA should produce a witness to testify pursuant to 21 C.F.R. § 20.1(c), as well as a copy of the Amended Consolidated Class Action Complaint (ECF No. 47), Judge Tigar's Order Granting in Part and Denying in Part Defendants' Motion to Dismiss (ECF No. 50), and the Protective Order (ECF No. 69). *See* ECF No. 129-1.

On November 30, 2023, the FDA responded with its determination that Lead Plaintiff's *Touhy* request did not meet the requirements of 21 C.F.R. § 20.1(c). ECF No. 99-3. The FDA

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98. Exhibits E, F, and G to the Joint Discovery Letter Brief are three deposition exhibits produced by ChemoCentryx and Exhibits H and I are excerpts of the deposition transcripts for Dr. Glassock and Dr. Maddrey. *Id.* at 2. Defendants subsequently filed a statement in support of sealing pursuant to Civil L.R. 79-5(f)(3). ECF No. 103. The Court granted the motion for good cause shown on February 16, 2024. ECF No. 123.

[5] The subpoena itself is dated November 14, 2023, as is the letter to the FDA accompanying the subpoena. In its response to the subpoena, the FDA stated that Lead Plaintiff's request for deposition testimony was dated November 20, 2023. ECF No. 99-3 at 2.

found that Lead Plaintiff failed "to provide any adequate explanation as to how it is in the public health interest for FDA employees to cease performing their official duties to prepare for and provide testimony in a civil action" to which the United States is not a party. *Id.* at 2. In addition, the FDA noted that "the information that you seek from an FDA witness's testimony is available from other sources." *Id.* at 3. Nevertheless, the FDA concluded its letter by stating that "[i]f agreed upon and authorized, FDA is amenable to providing testimony by an affidavit or sworn declaration." *Id.*

In a declaration in support of the Joint Discovery Letter Brief, counsel for Lead Plaintiff refers to "subsequent discussions" between the FDA and Lead Plaintiff concerning the FDA's willingness to provide written testimony, as well as the Protective Order and the possibility of Lead Plaintiff sharing discovery from the case with the FDA pursuant to court order, without Defendants' consent. ECF No. 99-2 ¶¶ 3–5. Counsel refers to correspondence from December 1 and 5, 2023, the latter of which included the FDA purportedly stating, "we are amenable to providing testimony (affidavit/declaration) if the court in the underlying litigation authorizes the sharing of discovery with the [FDA]." *Id.* ¶ 5. But this correspondence is not attached to the Joint Discovery Letter Brief.[6]

There is, however, a letter from the FDA, dated January 4, 2024, where the agency told Lead Plaintiff, "In your 21 C.F.R. § 20.1 request, you indicate that you have documents relevant to the requested testimony. FDA will need to review those records before determining the content and scope of any affidavit or declaration." ECF No. 99-1 at 2.

In addition, on March 11, 2024, six days after the hearing, Lead Plaintiff filed a Notice of Additional Filing Pursuant to the Court's Order (ECF No. 128). ECF No. 135. Lead Plaintiff attached a copy of its revised *Touhy* request, dated November 20, 2023, six days after the original

[6] Defendants object to the fact that Lead Plaintiff has refused to disclose all its communications with the FDA despite multiple requests. ECF No. 99 at 4–5. Lead Plaintiff claims that it is not required to do so, and that Defendants have failed to cite to any authority to the contrary. *Id.* at 3. The Court will rule on the Joint Discovery Letter Brief based on the record before it as provided by the parties. To the extent Defendants persist in their request to review all of Lead Plaintiff's communications with the FDA, there is nothing preventing them from requesting production of these communications as part of discovery in this case.

Touhy request. ECF No. 135-1. According to Lead Plaintiff, it added, "at the FDA's request," three additional sentences which reflect "Lead Counsel's meet-and-confer discussions with the FDA concerning the *Touhy* request":

> Please note that in lieu of deposition testimony, Lead Plaintiff is amenable to FDA's provision of testimony by affidavit or sworn declaration, at least as an initial matter. However, ChemoCentryx has taken the position that the protective order governing the dissemination of documents produced in this case does not permit Lead Plaintiff to share those documents with the agency outside of a deposition. Lead Plaintiff is working to resolve that dispute, but, if it is unable to do so, deposition testimony would be required.

Id.

II. LEGAL STANDARD

Because the parties dispute whether the Protective Order precludes Lead Plaintiff from disclosing certain material to the FDA, the Court sets forth the law and guiding principles that concern protective orders in federal litigation. Protective orders are a common feature of modern litigation in recognition of the parties' ongoing interests in privacy and the confidentiality of proprietary information. 8A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* (Wright & Miller) § 2035 (3rd ed. 2023) (citing *In re Mirapex Prod. Liab. Litig.*, 246 F.R.D. 668, 672–73 (D. Minn. 2007)).

Rule 26(c) of the Federal Rules of Civil Procedure provides that "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following: … forbidding the disclosure or discovery." Fed. R. Civ. P. 26(c)(1). "The purposes of a protective order under Rule 26 are to 'expedite the flow of discovery material, facilitate the prompt resolution of disputes over confidentiality, adequately protect confidential material, and ensure that protection is afforded only to material so entitled....'" *United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165 GHK (SS), 2016 WL 6542729, at *3 (C.D. Cal. Mar. 14, 2016) (quoting *In re Zyprexa Injunction*, 474 F. Supp. 2d 385, 397 (E.D. N.Y. 2007)).

As occurred in this case, parties often seek protective orders by way of agreement and stipulated order, which frequently authorize any litigant producing information to designate that

which is confidential and protected under the order. *See Wright & Miller* § 2043; United States District Court for the Northern District of California's Stipulated Protective Order for Standard Litigation, available at https://www.cand.uscourts.gov/forms/model-protective-orders/. This approach expedites production, reduces costs, and eliminates the need to litigate confidentiality protections on a document-by-document basis. *See* Manual for Complex Litigation § 11.432 (4th ed. 2004). "The most common kind of order allowing discovery on conditions is an order limiting the persons who are to have access to the information disclosed and the use to which these persons may put the information." Wright & Miller § 2043. "A protective order should be read in a reasonable and common sense manner so that its prohibitions are connected to its purpose." *Banga v. Equifax Info. Servs., LLC*, No. 14-CV-03038-WHO, 2016 WL 741963, at *5 (N.D. Cal. Feb. 25, 2016) (citation omitted); *see also In re Dual-Deck Video Cassette Recorder Antitrust Litig.*, 10 F.3d 693, 695 (9th Cir. 1993) ("For the protective order to comply with common sense, a reasonable reading must connect its prohibits to its purpose.").

III. DISCUSSION

Each side proffers several arguments as to whether the Court should interpret the Protective Order to allow Lead Plaintiff to disclose the deposition exhibits and testimony to the FDA. The Protective Order prohibits disclosure of information or items designated confidential, but Lead Plaintiff contends that exceptions to the prohibition established in Paragraph 7.2 of the Protective Order allow the disclosures that it seeks to make. Lead Plaintiff does not argue that the material at issue does not constitute information that may be treated as confidential under Rule 26(c).[7] Nor does Lead Plaintiff claim that the material is not "research, development or commercial information" as enumerated under Rule 26(c)(1). Each of the parties' arguments are addressed in turn below.

A. Paragraph 7.2(f) of the Protective Order

Lead Plaintiff argues that disclosure of the documents is allowed under Paragraph 7.2(f) of

[7] Paragraph 2.2 of the Protective Order defines "Confidential Information" as information or tangible things "that qualify for protection under Federal Rule of Civil Procedure 26(c)." ECF No. 69 at 1.

the Protective Order. ECF No. 99 at 2. Paragraph 7.2(f) allows disclosure, "during their depositions," to "witnesses in the action to whom disclosure is *reasonably necessary* and who have signed the 'Acknowledgment and Agreement to Be Bound' (Exhibit A), unless otherwise agreed by the Designating Party or ordered by the court." ECF No. 69 at 8 (emphasis added).

The Court is unpersuaded by Lead Plaintiff's contention that disclosure of documents designated as "confidential" to third-party witnesses for the purpose of providing written testimony is analogous to disclosure "during their depositions," pursuant to Paragraph 7.2(f) of the Protective Order. As Defendants point out, disclosure outside of the context of a deposition deprives them "of the opportunity to monitor the use of those documents and the opportunity to cross-examine a witness regarding those documents." ECF No. 99 at 5. Even if the third-party witness may later be questioned under oath, the late questioning does not create a sufficiently comparable set of circumstances, such that Paragraph 7.2(f)'s exception to the prohibition against disclosure is reasonably interpreted to cover written testimony. Paragraph 7.2(f) specifies, "Pages of transcribed deposition testimony or exhibits to depositions that reveal Protected Material must be separately bound by the court reporter and may not be disclosed to anyone except as permitted under this Stipulated Protective Order." ECF No. 69 at 8. The additional sentence in Paragraph 7.2(f), explicitly referencing "transcribed," as opposed to written testimony, demonstrates that the parties were not contemplating an exception broad enough to encompass written testimony.

Even if the Court were to determine that Paragraph 7.2(f)'s exception applied to written testimony, Lead Plaintiff has not established that disclosure of the confidential material to the FDA is "reasonably necessary" in this action. As an initial matter, Lead Plaintiff argues that it needs the FDA's written testimony because of Defendants' "repeated assertions in this case about what [the] FDA supposedly knew, thought, believed and said." ECF No. 99 at 3. According to Lead Plaintiff, "Defendants should not be permitted to make claims about [the] FDA's views while effectively blocking testimony from the agency on those subjects." *Id.* But the Court is not deciding whether Lead Plaintiff *needs* the FDA's testimony. Nor are Defendants seeking to quash the FDA subpoena. Defendants' objections are to the disclosure of confidential documents they produced in this litigation in a manner not contemplated by the Protective Order and without their

consent.

Lead Plaintiff argues that it needs to disclose these documents to "obtain meaningful testimony" from the FDA. *Id.* at 2. This contention likely stems in part from the FDA's January 4, 2024 letter, where the agency told Lead Plaintiff, "In your 21 C.F.R. § 20.1 request, you indicate that you have documents relevant to the requested testimony. [The] FDA will need to review those records before determining the content and scope of any affidavit or declaration." ECF No. 99-1 at 2. But there is no indication in the Section 20.1 *Touhy* request that the "documents relevant to the requested testimony" are the deposition exhibits and testimony that Lead Plaintiff wants to share. There is no description in that request of any kind of documents exchanged by the parties during discovery in this litigation.

The only documents described in detail are the "AdCom Materials," which are documents publicly released by the FDA on May 4 and 6, 2021, discussing data from the Advocate Trial, the history of the NDA, and summarizing ChemoCentryx's discussions with the agency. ECF No. 129-1 at 3–5. There is nothing preventing Lead Plaintiff from sharing the AdCom Materials with the FDA, if it has not done so already. In addition, Defendants note that the FDA was provided access to the minutes of DMC meetings which also contain discussion of data from the Advocate Trial. ECF No. 99 at 4. If Lead Plaintiff wants the FDA's testimony to show what the agency "knew, thought, believed and said" about avacopan, the NDA, and the Advocate trial, then the AdCom Materials and the DMC meetings would certainly be more relevant and useful than internal ChemoCentryx or DMC communications which did not involve any FDA personnel. Lead Plaintiff offers no explanation as to what the deposition exhibits and testimony would add above and beyond these documents which would allow Lead Plaintiff to obtain "meaningful testimony" from the FDA.

Notably, the declaration from counsel for Lead Plaintiff indicates that the FDA at one point said it was "amenable to providing testimony (affidavit/declaration) if the court in the underlying litigation authorizes the sharing of discovery with the [FDA]." ECF No. 99-2 ¶ 5. And the revised *Touhy* request, purportedly edited after meet-and-confer discussions with the FDA and at the FDA's request, provides that "ChemoCentryx has taken the position that the protective order

governing the dissemination of documents produced in this case does not permit Lead Plaintiff to share those documents with the agency outside of a deposition." ECF No. 135. Together, these documents suggest that Lead Plaintiff has in fact discussed with the FDA the possibility of providing it discovery from the case, and perhaps even that the FDA will not proceed with providing written testimony without reviewing these materials. However, as a non-party to the litigation, the FDA's desire to review the deposition exhibits and testimony is not necessarily dispositive of whether the Court should order disclosure of those documents over Defendants' objections. Allowing non-parties to dictate when information designated as confidential pursuant to a protective order is disclosed would undermine the effectiveness of that protective order and would discourage the free flow and exchange of discovery in civil litigation.

Defendants separately argue that disclosure is not necessary because the FDA already considered and rejected Lead Plaintiff's request for deposition testimony. ECF No. 99 at 5. Defendants emphasize that the FDA found Lead Plaintiff failed to meet the requirements of 21 C.F.R. § 20.1—that is, the request for deposition testimony was not in the public interest and did not promote the objectives of the Federal Food, Drug, and Cosmetic Act or the mission of the FDA. *Id.* According to Defendant, the fact that the "the testimony Plaintiff now seeks is in the form of an affidavit does not change the analysis." *Id.* This argument ignores the fact that the FDA is the one that volunteered to potentially provide written testimony, even after it denied the request for deposition testimony. ECF No. 99-3 at 3 ("If agreed upon and authorized, FDA is amenable to providing testimony by an affidavit or sworn declaration.") Nevertheless, based on the record before the Court, there is nothing to indicate that the FDA has *committed* to providing written testimony. This leaves open the possibility that if the Court grants Lead Plaintiff's request for a court order, Defendants' confidential information would be shared with a non-party who never testifies in the litigation.

Lead Plaintiff also argues that disclosure in this instance would be consistent with the purpose of the Protective Order. *Id.* ¶ 1 ("Disclosure and discovery activity in this action are likely to involve production of confidential, proprietary, or private information for which special protection from public disclosure…may be warranted.") According to Lead Plaintiff, the FDA is

ChemoCentryx's regulator, not competitor, it routinely obtains "confidential, proprietary, or private information" from each company it regulates, and it protects that information from public disclosure. ECF No. 99 at 2. But Paragraph 7.2 explicitly lists the circumstances under which Lead Plaintiff can disclose information marked as "confidential" by Defendants. ECF No. 69 at 8. Lead Plaintiff does not point to any legal authority outside of the Protective Order that would allow for disclosure of the confidential material that it seeks to provide to the FDA. As such, the Court must base its analysis of whether disclosure is allowed in this instance on the exceptions that the parties stipulated to and were approved by the Court.

B. Paragraph 7.2(g) of the Protective Order

Lead Plaintiffs also point to Paragraph 7.2(g) to argue in favor of disclosure. This provision allows disclosure to "the author or recipient of a document containing the information or a custodian or other person who otherwise possessed or knew the information." ECF No. 69 at 8. According to Lead Plaintiff, because Defendants represent that they disclosed all pertinent efficacy and safety data from the Advocate Trial to the FDA, then the FDA already possesses the confidential information contained in the deposition exhibits, which means that its employees can be considered "other person[s] who otherwise possessed or knew the information." *Id.* But just because the FDA eventually obtained the underlying data from the Advocate Trial does not mean it has any knowledge of internal ChemoCentryx or DMC communications which reflect the author's opinions about that data. Those opinions and commentary on the data also form part of the information marked as "confidential" by Defendants pursuant to the Protective Order.

C. Admissibility and Probative Value of FDA Testimony

Finally, Defendants argue that disclosure of their confidential documents to the FDA to obtain the agency's written testimony should not be permitted because the testimony would be inadmissible, and because it is irrelevant to the securities class action case Lead Plaintiff has filed against Defendants. ECF No. 99 at 5–6. The Court rejects Defendants' admissibility arguments outright because "[r]elevant information need not be admissible to be discoverable." *Rothman v. Rothman*, 2022 WL 20208933, at *1 (N.D. Cal. May 17, 2022). More importantly, the Court is not being asked to determine the admissibility or even the relevance of any FDA written

testimony. The question before the Court is much narrower: should the Court issue an order permitting Lead Plaintiff to disclose deposition exhibits and testimony designated as confidential by Defendants to the FDA? Lead Plaintiff has failed to demonstrate that such an order is consistent with what the parties agreed to in the Protective Order.

IV. CONCLUSION

For the reasons detailed above, the Court hereby **DENIES** Lead Plaintiff's request in the Joint Discovery Letter Brief for a court order allowing it to share with the FDA any material designated by Defendants as "confidential" under the Protective Order governing this case.

IT IS SO ORDERED.

Dated: March 11, 2024

LISA J. CISNEROS
United States Magistrate Judge